Remarks

The Office Action mailed June 25, 2009 has been received and reviewed. Claims 17-30 having been amended herein, claims 31 and 32 having been withdrawn from consideration by the Examiner, no claims having been cancelled herein, and claims 33 and 34 having been added herein, the pending claims are claims 17-34. Reconsideration and withdrawal of the rejections are respectfully requested.

Capitalization in claims 17-30 has been amended. Claim dependency in claims 18-30 has been amended. Punctuation in claim 28 has been amended.

Support for new claim 33 may be found throughout Applicants' Specification and specifically at, for example, page 5, lines 28-31 (of the Substitute Specification (clean copy)), the Examples, and claims 17 and 28.

Support for new claim 34 may be found throughout Applicants' Specification and specifically at, for example, page 5, lines 28-31 (of the Substitute Specification (clean copy)), the Examples, and claims 17, 27, and 32.

Entry and consideration of the claim amendments are respectfully requested.

Substitute Specification

The present amendments in this Substitute Specification include changes to formatting (e.g., deletion of headers, change of line spacing, addition of line numbers, removal of page numbers in translation). The present amendments in the enclosed Substitute Specification also include a change in capitalization on page 1 ("Filed" to "filed"), the addition of "What is claimed is:" on page 11, and a change in the abstract title ("Summary" to "Abstract") on page 14.

Please note that the text of the Abstract in the enclosed Substitute Specification is the same as that in the English-language translation provided upon filing, but is different than the Abstract shown in the publication of the present application (U.S. Patent Application Publication No. 2006/0159630 A1).

Applicants respectfully submit that the Substitute Specification contains no new matter.

Claim Objections

The Examiner objected to claims 17-30 because of an informality, namely that the term "Dental" should be rewritten as "dental." Claims 17-30 have been amended as suggested by the Examiner. Reconsideration and withdrawal of the objections to claims 17-30 regarding the term "Dental" are respectfully requested.

The Examiner also objected to claims 18-30 under 37 C.F.R. § 1.75(c) for depending from claims that are cancelled. Claims 18-30 have been amended to depend from pending claims, thereby obviating the objection. Reconsideration and withdrawal of the objections to claims 18-30 regarding claim dependencies are respectfully requested.

The 35 U.S.C. §112, Second Paragraph, Rejection

The Examiner rejected claim 23 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner alleged that there was insufficient antecedent basis for the phrase "the liberation of the substance" recited in claim 23. Applicants traverse the rejection.

Claim 23 has been amended to depend from claim 21, which recites the phrase "the substance being liberated," thereby providing antecedent basis for "the liberation of the substance" (e.g., claim 23).

Applicants submit that the amendment obviates the §112, second paragraph, rejection of claim 23. Reconsideration and withdrawal of the §112, second paragraph, rejection of claim 23 are respectfully requested.

The Examiner rejected claims 19, 21, 22, and 24-26 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner alleged that claims 19-21 and 24 recite both a product and a process requiring active steps as reflected in the phrase

"stored in the area," and are thus rejected on the theory that the claims are directed to neither a "process" nor a "product" exclusively. Applicants traverse this rejection.

The Examiner relied upon the allegation that claims 19, 21, and 24 recite both a product (a dental material) and a process requiring active steps as reflected in the phrase "stored in the area," as the basis of rejecting claims 19, 21, 22, and 24-26 for being directed to neither a process nor a product exclusively. It is not an accurate statement of patent law that a claim may be "thus rejected (along with its dependent claims on the [Examiner's] theory that the claim is directed to neither a 'process' nor a 'product' exclusively" (Office Action dated June 25, 2009, page 3). The Examiner's statement of the law and application thereof are too broad. (*See* M.P.E.P. §§ 2173.05(p) ("[t]here are many situations where claims are permissively drafted to include a reference to more than one statutory class of invention" (emphasis added)) and 2173.05(p)(I) (product-by-process claims).)

Thus, without acquiescing to the present rejection and to the extent that Applicants understand the rejection and basis thereof, Applicants disagree and present the following remarks in support of Applicants' traversal.

Applicants have interpreted the Examiner's statement that "[c]laims 19, 21, and 24 are thus rejected (along with its dependent claims)" to mean that claims 22, 25, and 26 are rejected due only to their dependence from one of claims 19, 21, and 24. If this interpretation is not correct, appropriate correction and clarification are respectfully requested.

Claim 19 recites a dental material "wherein the substance is . . . stored in the area between the dentin or melt and the dental material." Thus, claim 19 merely recites the environment in which the substance is located (e.g., stored), but does not recite a process requiring active steps, as alleged by the Examiner.

Claim 21 recites a dental material "wherein the substance is . . . stored in the area between the dentine or melt and the dental material on the surface of the dental material." Similarly, claim 21 merely recites the environment in which the substance is located (e.g., stored), but does not recite a process requiring active steps, as alleged by the Examiner.

Claim 24 recites a dental material "wherein the substance is . . . stored on the surface of the dental material in the area between the dentin or melt and dental material." Similarly, claim 24 merely recites the environment in which the substance is located (e.g., stored), but does not recite a process requiring active steps, as alleged by the Examiner.

For at least these reasons, Applicants submit that each of claims 19, 21, and 24 (and claims depending therefrom) does not violate §112, second paragraph. Reconsideration and withdrawal of the §112, second paragraph, rejections of claims 19, 21, 22, and 24-26 are respectfully requested.

The 35 U.S.C. §101 Rejection

The Examiner rejected claims 19, 21, 22, and 24-26 under 35 U.S.C. §101 as being directed to non-statutory subject matter because the claims are directed to both a product and a process. Applicants traverse this rejection.

The Examiner relied upon the allegation that claims 19, 21, and 24 recite both a product (a dental material) and a process requiring active steps as reflected in the phrase "stored in the area," as the basis of rejecting claims 19, 21, 22, and 24-26 for being directed to neither a process nor a product exclusively. It is not an accurate statement of patent law that a claim may be "thus rejected (along with its dependent claims on the [Examiner's] theory that the claim is directed to neither a 'process' nor a 'product' exclusively" (Office Action dated June 25, 2009, page 3), for at least the reason that there is no such requirement. (*See* M.P.E.P. §§2173.05(p) ("There are many situations where claims are permissively drafted to include a reference to more than one statutory class of invention" (emphasis added)) and 2173.05(p)(I) (product-by-process claims).)

For at least the reasons provided hereinabove regarding the §112, second paragraph, rejection of claims 19, 21, 22, and 24-26, Applicants respectfully submit that each of claims 19, 21, 22, and 24-26 does not violate §101.

Reconsideration and withdrawal of the §101 rejection are respectfully requested.

The 35 U.S.C. §102 Rejection

The Examiner rejected claims 17-26 under 35 U.S.C. §102(a) as being anticipated by Wagner et al. (International Publication No. WO 2002/006820; U.S. Patent Application Publication No. 2004/0029171 is the national stage application for WO 2002/006820 and was used by the Examiner for translation purposes). Applicants traverse the anticipation rejection.

"[F]or anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly." M.P.E.P. §706.02(V) (emphasis added).

Claim 17 (as amended) recites, "A dental material comprising at least one substance whose bacteriostatic and/or bactericidal efficacy is formed in the presence of intraoral microorganisms." (Emphasis added.)

For the recited substance, the Examiner cited Wagner et al.'s disclosure of methylene blue and benzofurazan derivatives, stating, "Although defined in the reference as indicator substances, it is submitted that when methylene blue and the benzofurazan derivative come into physical contact with the microbe or microbe enzyme in the saliva, then the bacteriostatic or bactericidal efficacy is formed since both methylene blue and the benzofurazan derivative are also antibacterial agents." (Office Action dated June 25, 2009, page 5.) Applicants earnestly disagree.

Applicants respectfully submit that the Examiner has not identified within Wagner et al. a dental material that includes at least one substance whose bacteriostatic and/or bactericidal efficacy is formed in the presence of intraoral microorganisms. Specifically, the Examiner has improperly equated a substance having antimicrobial properties (without regard for the presence of intraoral microorganisms) with a substance whose bacteriostatic and/or bactericidal efficacy is formed in the presence of intraoral microorganisms. It is submitted that whatever bacteriostatic and/or bactericidal efficacy is present in methylene blue and benzofurazan, it is present in the structure of the compounds, and the Examiner has failed to identify any disclosure of Wagner et al. that the efficacy of the cited compounds is formed in the presence of intraoral microorganisms.

For at least this reason, the anticipation rejection of claims 17-26 must fail.

The Examiner rejected claims 17-20, 22, and 23 under 35 U.S.C. §102(b) as being anticipated by Bowen (U.S. Patent No. 5,603,921). Applicants traverse the anticipation rejection.

"[F]or anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly." M.P.E.P. §706.02(V) (emphasis added).

Applicants respectfully submit that Bowen fails to disclose or suggest a dental material that includes at least one substance whose bacteriostatic and/or bactericidal efficacy is formed in the presence of intraoral microorganisms.

Bowen discloses use of a dental floss that includes polyethylene glycol impregnated with an antimicrobial (e.g., chlorhexidine). Bowen discloses that use of the floss on teeth results in small deposits on the teeth of polyethylene glycol and the antimicrobial.

However, Bowen fails to disclose a substance whose bacteriostatic and/or bactericidal efficacy is formed in the presence of intraoral microorganisms. Rather, Bowen's antimicrobial (e.g., chlorhexidine) has efficacy that is formed before being in the presence of intraoral microorganisms.

For at least this reason, the anticipation rejection of claims 17-20, 22, and 23 must fail.

The Examiner rejected claims 17-20, 22, 23, and 28-30 under 35 U.S.C. §102(b) as being anticipated by Pflug et al. (International Publication No. WO 98/48766). Applicants traverse the anticipation rejection.

"[F]or anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly." M.P.E.P. §706.02(V) (emphasis added).

Applicants respectfully submit that Pflug et al. fail to disclose or suggest a dental material that includes at least one substance whose bacteriostatic and/or bactericidal efficacy is formed in the presence of intraoral microorganisms.

Applicants note that Pflug et al. is acknowledged at page 2, lines 1-6 of the Specification (Substitute Specification (clean copy)), which states that the use of triclosan in dental materials is

limited in time since the triclosan is dissolved and moved away as a function of its initial concentrations and the saliva flow. Triclosan is a di-phenylether substance bearing three chloro substituents and one hydroxy group. Thus, besides the hydroxy group there is no reactive substituent present and the substance remains stable especially in the oral environment (as confirmed by WO-98/48766; page 4, lines 3-5). The antimicrobial activity of triclosan is caused by the structure as it is. Moreover, triclosan is said to have a low water solubility (WO-98/48766; page 6, lines 1-4).

In direct contrast, the present claims recite at least one substance whose bacteriostatic and/or bactericidal efficacy is formed in the presence of intraoral microorganisms. For example, if taurolidine is used instead of triclosan, then a more efficient and completely different manner of antimicrobial reactivity can be achieved. Taurolidine contains 4 (basic) amino groups, 2 sulfur atoms and is a reactive molecule which "decomposes" during reaction and releases formaldehyde, which is assumed to be the antimicrobial and reactive substance. Taurolidine is also water-soluble (see "Taurolidine sc-202827," Santa Cruz Biotechnology, Inc., retrieved from the internet on Sept. 25, 2009, <URL:http://www.scbt.com/datasheet-202827.html>, 1 page, attached as Exhibit A).

Thus, from a chemical perspective, the structure and reactivity of the presently claimed substances (e.g., taurolidine) cannot be compared with the structure and reactivity of triclosan.

As can be taken from the description and especially from the examples of the present Specification, it has been found that the presently recited substances (e.g., taurolidine) can be incorporated into various dental materials containing polymerizable components and their respective initiators.

This is surprising. For example, with respect to silicones (typically curing in the presence of a platinum catalyst), the person skilled in the art would expect that the platinum catalyst is damaged either by the nitrogen atoms or the sulfur atoms being present in the taurolidine molecule (see, e.g., Example 1).

The same holds true with respect to polyether impression materials. Those materials cure cationically. The initiator basically generates H+ ions. It is surprising that the curing

mechanism still functions despite the fact that taurolidine contains basic nitrogen atoms (see, e.g., Example 2).

Finally, in view of the fact that triclosan has a low water solubility and taurolidine has a good water solubility, the person skilled in the art would not be motivated to incorporate this substance into the material described in Pflug et al., because the skilled person would expect that this substance is released from the dental material rather quickly, which would be counterproductive in view of the effect which is intended to be achieved by Pflug et al.

The 35 U.S.C. §103 Rejection

The Examiner rejected claim 27 under 35 U.S.C. §103 as being unpatentable over Pflug et al. (International Publication No. WO 98/48766) in view of Geistlich et al. (U.S. Patent No. 4,096,241).

Applicants submit that the Examiner has not established a *prima facie* case of obviousness of claim 27 over Pflug et al. in view of Geistlich et al. for at least the reason that one of skill in the art would not have been motivated based on the cited documents to make a combination as proposed by the Examiner and would not have had a reasonable expectation of success in doing so.

The Examiner admitted that Pflug et al. fails to disclose taurolidine. Thus, the Examiner relied upon Geistlich et al. for the disclosure of taurolidine and alleged that it would have been obvious to use Geistlich et al.'s taurolidine in the dental materials of Pflug et al. The Examiner alleged that the motivation to make such a combination is maintaining antimicrobial properties known to have low toxicity over long periods of time.

It is submitted that combining Pflug et al. and Geistlich et al. is not obvious. Geistlich et al. disclose oral care compositions, but not those with curable or hardenable compositions.

One of skill in the art would not have had a reasonable expectation of success. For example, one of skill in the art would not have expected that the curable compositions of Pflug et al. would still be curable and that the curing mechanism would not be negatively affected by the addition of Geistlich et al.'s taurolidine. Moreover, one of skill in the art would not have

expected that taurolidine would still be effective when added to the curable compositions of Pflug et al.

It may not be necessarily concluded that if one takes a substance (e.g., taurolidine) that has been used in non-curable compositions (e.g., mouthwashes, dentrifices, etc.), then that substance can also be used in curable compositions. When a substance is put into a curable composition, the substance will typically remain within the composition, especially if the composition is cured. Thus, it would be expected that the efficacy of the substance would be dramatically reduced (e.g., as compared to the substance in a liquid composition, such as mouthwash).

Surprisingly, Applicants found that a substance (e.g., taurolidine) whose bacteriostatic and/or bactericidal efficacy is formed in the presence of intraoral microorganisms may be incorporated into a curable composition. Moreover, the structure of Geistlich et al.'s taurolidine is very much different from that of Pflug et al.'s triclosan and, thus, it may be assumed that the mechanism used by triclosan to kill germs may be different from that used by taurolidine.

The Examiner, in simply stating that it would have been obvious to exchange Pflug et al.'s triclosan with Geistlich et al.'s taurolidine, has not provided adequate and proper reasoning sufficient to establish a *prima facie* case of obviousness. Once the solution to a problem is known, one can be tempted to import hindsight and allege it is obvious. Thus, Applicants respectfully submit that the Examiner's combination of Pflug et al. in view of Geistlich et al. must have been as a result of improper hindsight analysis.

As recently reasserted in *Princeton Biochems., Inc. v. Beckman Coulter, Inc.*, 411 F.3d 1332; 75 USPQ2d (BNA) 1051 (Fed. Cir. 2005), 35 U.S.C. §103 specifically requires an assessment of the claimed invention "as a whole." This "as a whole" assessment of the invention requires a showing that an artisan of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would have selected the various elements from the cited references and combined them in the claimed manner. In other words, 35 U.S.C. §103 requires some suggestion or motivation, before the invention itself, to make the new combination. *See In re Rouffet*, 149 F.3d at 1350.

In *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727; 167 L.Ed.2d 705; 82 USPQ2d (BNA) 1385 (2007), the U.S. Supreme Court has acknowledged the utility of this "teaching, suggestion, motivation" inquiry when determining the obviousness of an invention by recognizing that the inquiry arose from "helpful insight" of the Court of Customs and Patent Appeals. The inquiry arose as a guard against a finding of obviousness where an examiner or a court was able to find all of the elements of an invention in the prior art, but without any suggestion or motivation to combine the prior art references that described the elements in question. The Court reiterated that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." 167 L.Ed.2d at 14.

This "as a whole" instruction in 35 U.S.C. §103 prevents evaluation of the invention part by part, aided by the template of Applicants' disclosure. Without this important requirement, an obviousness assessment might reduce an invention into its component parts, then find a reference corresponding to each component. This type of assessment would import hindsight into the obviousness determination by using the invention as a roadmap to find its prior art components. The U.S. Supreme Court cautioned against such analysis in *KSR*, stating, "A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning." (167 L.Ed.2d at 725, citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "'guard against slipping into the use of hindsight'" (383 U.S. at 36, quoting *Monroe Auto Equipment Co. v. Heckthorn Mfg. & Supply Co.*, 332 F. 2d 406, 412 (6th Cir. 1964))).

For at least the reasons provided herein, the Examiner has failed to establish a *prima facie* case of obviousness of claim 27. Applicants respectfully request reconsideration and withdrawal of the obviousness rejection of claim 27.

Summary

It is respectfully submitted that all of the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted
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CERTIFICATE UNDER 37 CFR §1.8:
The undersigned hereby certifies that this paper is being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 CFR §1.6(a)(4) to the Patent and Trademark Office addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 23rd day of October 2009.

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